Spine Care Institute

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HOSPITAL FOR SPECIAL SURGERY

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July 10, 2000

Ms. Kathy Eberhart
Food & Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike, Ste 200
North Rockville, MD 20852-1448
HFM42

Dear Ms. Eberhart:

I am submitting this letter to inform you of my position regarding the classification of human tissues as medical devices.

I am aware that the FDA panel will convene on August 2nd to sponsor an open public meeting on "Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair."

I am in agreement with the FDA regulating the safety of tissue that tissue and bone banks currently provide; however, I oppose the proposal that the FDA regulate some types of allograft bone and tissues as medical devices. If such a proposal were passed, this would severely curtail the supply of bone and tissue products available on which I currently rely for treating patients.

I therefore strongly oppose the proposed FDA regulation.

Thank you for your consideration of my concerns.

Sincerely,

M.D./BP

Frank P. Cammisa, Jr., M.D., F.A.C.S.
Director, SpineCare Institute
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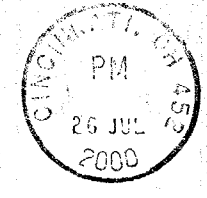

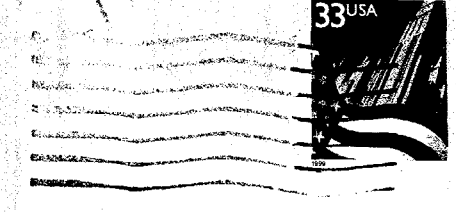

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